NATIONAL CHILD SURVIVAL AND SAFE MOTHERHOOD PROGRAMME

PROGRAMME INTERVENTIONS

IMMUNIZATION
COLD CHAIN

MCH DIVISION
Ministry of Health and Family Welfare
Government of India
New Delhi

NATIONAL HEALTH POLICY MCH GOALS

	Current Level	2000
A. REDUCTION OF MORTALITY RATES (/1000)		
Infant Mortality Rate (1992)	79	< 60
Perinatal Mortality Rate (1991)	46	< 35
Under 5 Mortality Rate (1991)	26.5	< 10
Maternal Mortality Rate (Est. 1992)	4	< 2
B. REDUCTION IN THE PROPORTION OF LBW (%)		
Under Weight Babies (Est. 1992)	30	10
C. SERVICES (% COVERAGE)		
Immunization - Infants (1992-93)	87.6	85
- Pregnant Women	81.6	100
Deliveries by trained personals (91)	46.3	100
Antenatal care (Est. 1992)	79	100
D. PREVENTION OF BLINDNESS DUE TO VIT. A DEFICIENCY		
Blindness Control (%)		.3

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PREFACE

The universal immunization coverage of 27 million pregnant women and 25 million infants, annually, is one of the most important interventions under the Child Survival and Safe Motherhood Programme. Over 650 million doses of vaccines are used annually under the Immunization Programme.

Immunization coverage levels have more than doubled as compared to 1984-85. The average annual number of reported cases of vaccine preventable diseases has declined from 5.16 lakhs during the period 1980-84 to 1.95 lakhs during the period 1990-93. The infant mortality rate has dropped from 104 per 1000 live births in 1984 to 79 in 1992 and the child mortality rate from 41.2 per 1000 children under five years of age in 1984 to 26.5 in 1991. As a result in the fall in the child mortality rate, more than 16.8 lakh deaths are prevented annually as compared to the number of deaths in 1984.

Despite overall high immunization coverage levels there are many areas where coverage levels are low. Supplementary efforts are also required to achieve the goals of polio eradication, neonatal tetanus elimination and measles control.

This manual describes the objectives and strategies of the Immunization Programme, supplementary activities for achieving polio eradication and neonatal tetanus elimination, the essential elements of the cold chain system, procedures for indenting vaccines and monitoring utilization of vaccines and other supplies as well as maintenance of the cold chain equipment. Surveillance, which is critical for the successful implementation of the Immunization Programme and other interventions under the Child Survival and Safe Motherhood Programme, is covered in a separate manual.

I. THE IMMUNIZATION PROGRAMME

1. THE IMPORTANCE OF THE IMMUNIZATION PROGRAMME

1.1 Diphtheria, pertussis, tetanus, measles, poliomyelitis and childhood tuberculosis have high case fatality rates in infants and young children and can lead to lifelong sequelae in those who survive. Vaccines, for the prevention of cases of the above six diseases are safe, effective and affordable. Immunization of children and pregnant women is considered to be one of the most cost-effective public health interventions.

1.2 Vaccine preventable diseases (VPDs) were widespread and a major cause of childhood morbidity, mortality and life long physical and mental disabilities, prior to the immunization programme. The recorded incidence of VPDs, and infant and child mortality rates have declined significantly in the last decade. Nearly 1.7 million lives of children under 5 years of age were saved in 1992 alone as a result of the fall in the mortality rates as compared to the baseline rates in 1984 (year prior to UIP). However, an estimated 3 million deaths in this age-group still occur which can be largely prevented through further increase of immunization coverage levels and by improving existing practices for the management of diarrhoea, ARI, maternal and newborn care.

1.3 Although the number and scale of outbreaks has also declined, these have not been completely eliminated. The risks of large outbreaks will increase if coverage levels are not sustained.

1.4 Sustaining high levels of immunization coverage is essential to meet the goals of elimination of neonatal tetanus, eradication of poliomyelitis and control of other vaccine preventable diseases.

1.5 The success of the Child Survival and Safe Motherhood (CSSM) Programme is also dependent on the logistics and access developed under the Immunization Programme. A drop in immunization coverage levels and increase in the incidence of vaccine preventable diseases will adversely affect the credibility of the health staff and the health care system and have a negative impact on the acceptance of other interventions included in the CSSM Programme.

2. PURPOSE OF TRAINING

- To sustain high levels of immunization coverage and maintain high quality of immunization services
- To eliminate high risk pockets of low coverage
- To establish effective strategies for neonatal tetanus elimination, polio eradication and measles control.
- To maintain a reliable cold chain system.

3. CURRENT STATUS

3.1 The Immunization Programme was launched in 1978. In 1985-86, a district wise phasing of the Programme was adopted with the goal of achieving universal immunization coverage of infants and pregnant women in the district. All districts in the country were covered over a period of five years from 1985-86 to 1989-90. Additional inputs were provided for establishing the cold chain system and for training medical and paramedical personnel. The surveillance system was also developed as an essential element of the immunization programme. The objective of UIP was to rapidly increase immunization coverage levels in the districts under the Programme and to improve quality of services. It was also aimed to achieve self-sufficiency in vaccine production. District wise monitoring was introduced. Universal Immunization Programme (UIP) received added urgency when it was taken up as one of the five Technology Missions in 1986.

3.2 Since 1989-90, nearly 80% of the 27 million pregnant women and over 85% of the 25 million infants are receiving the full course of the vaccines, annually. Immunization coverage levels have more than doubled since 1985-86. Dropout rates have reduced and children are being increasingly brought to the immunization sessions at the right age. Awareness about the immunization programme and demand for the services are high. The reported incidence of the vaccine preventable diseases has declined significantly even though the surveillance system has improved. In large parts of the country the incidence of poliomyelitis has reached negligible levels and neonatal tetanus has been eliminated. The infant mortality rate has dropped from 104 per 1000 live births in 1984 to 79 in 1992. The child mortality rate has declined from 41.2 per 1000 children under 5 years of age in 1984 to 26.5 in 1991.

3.3 The problems that need to be now addressed are:

- Identify districts where coverage levels are below 50% and areas within other districts, such as urban slums, peri-urban areas and remote villages. Additional efforts must be put in and micro-plans prepared to increase immunization coverage levels in these areas.
- Over-reporting of immunization coverage levels in a number of districts remains a matter of concern. Since these districts also have comparatively weaker surveillance systems, there is a risk of false sense of security and the inability to initiate prompt and appropriate action in the event of outbreaks.
- In the districts with sustained high levels of immunization coverage, the identification of high risk pockets and intensification of immunization services is a high priority. The efforts and resources must be scaled up in order to achieve this task while sustaining high coverage in the other parts of the district.

- Initiate supplementary activities in all districts to achieve the goal of neonatal tetanus elimination and at least 90% reduction in the incidence of measles by 1995. By the end of 1997, all districts must become polio free zones.

4. STRATEGY

4.1 The strategy of the Immunization Programme is to make routine immunization services available on a regular basis on fixed days at readily accessible fixed sites. A cancellation of an immunization session is a breach of trust with the community and should be avoided at all costs. Sessions on an unscheduled day should be held only in case of an emergency such as an outbreak or for conducting supplementary activities for polio eradication. The community should be informed of these sessions in advance.

4.2 All health facilities will provide immunization services on fixed days. The periodicity of the services (daily, weekly, fortnightly or monthly) will depend on the number of children immunized in these centres. Outreach visits will be made to all large villages at least once a month by the ANM of the subcentre covering these villages. The place of the immunization site in the village should be fixed.

4.3 Efficacy of the vaccines in preventing disease is optimal if the full course of the potent vaccine is given at the right age. Efforts would be made to start the immunization of children at 6 weeks of age and complete the three doses of OPV and DPT by 14 weeks or as soon as possible, thereafter. Measles vaccine is to be given between 9-12 months. It will be aimed to cover all infants before they reach their first birthday. Children born in the institutions will be given a dose of BCG and OPV before discharge. The dose of OPV '0 dose' will be additional and the primary series of three doses will start at 6 weeks of age.

Older unimmunized children will be given vaccines ON DEMAND if brought to the sessions. Older children in high risk pockets may be vaccinated in anticipation of an outbreak or during the supplementary activities for polio eradication.

4.4 Minor illnesses, including mild fever, coughs and colds as well as malnutrition, are not a contra-indication to immunization. Immunization should be deferred only if the children are seriously ill or have high fever as any aggravation in the condition of the child may be attributed to immunization. The children should, however, be immunized as soon as they recover. The longer the immunization is delayed, the longer the child is exposed to the risk of infection. Case fatality rates, especially following measles, are high in malnourished children. In case of history of convulsions, DT vaccine should be given in place of DPT vaccine. All vaccines can be given to a child with diarrhoea. The dose of OPV should, however, be repeated during the next immunization session.

MALNUTRITION, LOW GRADE FEVER, MILD RESPIRATORY INFECTIONS, DIARRHOEA AND OTHER MINOR ILLNESSES ARE NOT A CONTRA-INDICATION TO IMMUNIZATION

4.5 All the vaccines will be available at an immunization session and the child should not be made to return due to non-availability of any vaccine. A child can be given more than one vaccine at the same session, such as DPT and OPV. If vaccines are being given by injection such as BCG and DPT or DPT and measles, the sites of the injections should be different. The vaccines should be injected by using a separate sterile syringe and needle for each injection.

4.6 Vitamin A should be given along with measles vaccine at 9 months of age. If the schedule for OPV has not been completed, a dose of OPV can be given at the same time along with vitamin A solution.

NATIONAL IMMUNISATION SCHEDULE

FOR PREGNANT WOMEN

❖ Early in Pregnancy	: TT-1 or Booster
❖ One month after TT-1	: TT-2

FOR INFANTS

❖ At birth *	: BCG and OPV-0 dose
❖ At 6 weeks	: BCG : DPT-1 and OPV-1
❖ At 10 weeks	: DPT-2 and OPV-2
❖ At 14 weeks	: DPT-3 and OPV-3
❖ At 9 months	: Measles
❖ At 16 - 24 months	: DPT and OPV
❖ At 5-6 years	: DT

The second dose of DT should be given at an interval of one month if there is no clear history or documented evidence of previous immunization with DPT.

❖ At 10 and at 16 years	: TT

The second dose of TT vaccine should be given at an interval of one month if there is no clear history or documented evidence of previous immunization with DPT, DT or TT vaccines.

* For Institutional Deliveries

4.7 If the sessions are held regularly, quality of the services are satisfactory, mothers informed of the immunization schedule, the attendance at the immunization sessions are likely to be in the estimated range. If fewer than expected number of children turn up for any session,

vaccine vials should be opened and the children immunized. Children should not be returned unimmunized to keep 'wastage rates' of vaccines low. If the attendance is routinely low, reasons for poor acceptance of services should be identified and corrected.

5. ROLE OF MEDICAL OFFICERS

5.1 The medical officers of the PHCs must ensure universal immunization of children in their areas and must monitor the programme to sustain quality of services.

5.2 The medical officers must also ensure that the distribution of essential supplies are regular and that all subcentres have adequate supplies. Sufficient number of syringes and needles should be available at each subcentre.

5.3 They must provide additional assistance to pockets of low coverage. The type of assistance will depend on area-specific problems. If the low coverage is due to a long-term vacancy, special immunization camps may have to be organized by mobilizing resources from other areas. If the coverage is due to poor acceptance of services, IEC activities may have to be stepped up.

5.4 The PHC medical officer must also monitor performance and analyze surveillance reports.

5.5 The peripheral health staff must receive support from the medical officer if there is any adverse reaction following immunization. Monitoring of adverse events following immunization is important to detect programmatic lapses. Adverse events should be reported and investigated immediately. Serious adverse events including death following immunization must be reported within 24 hours. Other children vaccinated in the session should be examined to check for reactions and to provide treatment, if required. Cluster of cases (more than one case) is expected if the reaction was due to a programmatic error. Clustering of cases can also occur if the cause of the symptoms was due to incidental causes such as an infection. Other non-immunized children of the same age-group in the neighbourhood of the affected child should also be examined to rule out temporal relationship between reported adverse effect and immunization.

5.6 The vaccine issue register must be checked periodically to ensure that the vaccines are being taken out only on scheduled days. The temperature record forms of the ILR and the freezer must be checked weekly.

5.7 Medical Officers must ensure:

- Universal immunization coverage to all infants starting at 6 weeks of age or as early as possible thereafter.
- That the children receive full course of the vaccines by reducing dropout rates.

THE DAY AND TIME OF IMMUNIZATION SESSION SHOULD BE FIXED AND SHOULD BE PROMINENTLY DISPLAYED AND KNOWN TO THE COMMUNITY

- That the vaccines given to the children are potent by maintaining an efficient cold chain system.
- Regularity of services by having a 'fixed-day' and 'fixed-site' immunization sessions so that the community is aware of the time and place and vaccine supplies to the periphery can be monitored.
- All vaccines must be available at each immunization session.
- Vials opened for an immunization session are **NOT REUSED** for a subsequent session.
- Vaccines are issued on the day of the session or the previous evening only after checking that the **FOUR** icepacks of the vaccine carrier are fully frozen.
- vaccines which can be utilized during the day only are to be issued.
- single sterile syringe and needle is used for each injection. The syringes and needles must be sterilized before reuse.
- Mother-infant card are issued to all pregnant women and continued for use of the infant. The Mother-Infant Immunization Card, which includes items on antenatal care, iron and folic acid and Vitamin A is an important major tool for providing information to the family and must be filled at the time of providing these services. The counterfoil must be preserved by the health worker and utilised for follow up of the "drop outs". Ensure that drop outs are traced and appropriate immunizations given.

6. ROLE OF PRIVATE PRACTITIONERS AND NGOS

6.1 The private practitioners and the NGOs can help in increasing immunization coverage levels. If there are any NGOs who are active in the area of the PHC, their help can be sought in creating awareness and demand generation. They can also help in notifying cases of vaccine preventable diseases.

6.2 The private practitioners and the NGOs can also assist in the organization of special immunization camps in pockets of low coverage and the supplementary activities for the eradication of poliomyelitis and elimination of neonatal tetanus.

6.3 If the private practitioners and the NGOs are also providing immunization services and have qualified personnel and cold storage facilities, vaccines and mother-infant cards can be made available to them. Records of immunization performed should be collected and included in the performance reports.

II. ERADICATION OF POLIOMYELITIS

1. Among the vaccine preventable diseases, poliomyelitis is a well recognized and feared disease in the community due to the atrophy of the affected muscles that results following the disease. Prior to the immunization programme, poliomyelitis was the cause of lameness in two out three children with the physical handicap.

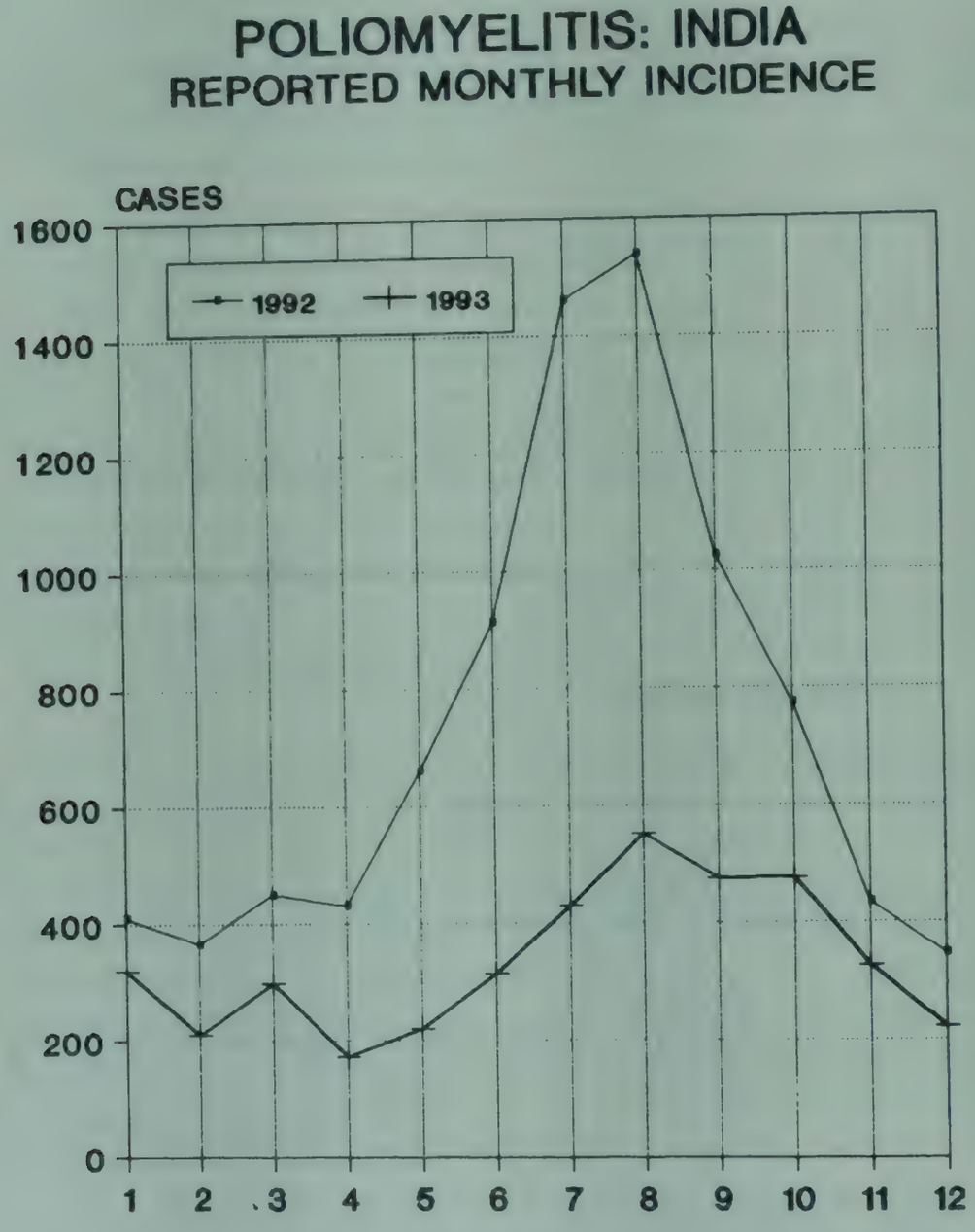
2. Poliomyelitis is caused by three types of polio viruses. Type I polio virus is predominantly isolated in children with paralysis. It is estimated that for every child with paralytic poliomyelitis, at least 100 other children are affected who have either no symptoms or have only non-specific symptoms of a mild illness. These children also excrete polio viruses and contaminate the environment. Man is the only host for polio viruses.

3. Oral polio vaccine is effective in preventing poliomyelitis. Many countries have successfully become polio free zones by immunizing all susceptible children through high immunization coverage levels and by eliminating foci of infection by organizing supplementary activities in addition to sustaining high levels of immunization coverage. In 1993, 141 countries reported zero cases to the WHO, including 106 countries which reported zero cases for three consecutive years. The World Health Assembly in May 1988 adopted the goal of global eradication of poliomyelitis by the year 2000. The goal of polio eradication means not only the absence of clinically identifiable cases of poliomyelitis, but also the elimination of the wild polio viruses from the environment so that future generations are free of the risk of the disease without immunization.

4. Oral polio vaccine provides immunity to vaccinated children. The viruses in the vaccine also multiply in the gut and are excreted in the environment. This ability of the vaccine viruses to multiply in the guts of the children is used in the strategy for 'mop-up' rounds. By immunizing close to 100% susceptible children in an area, wild polio viruses which cause paralytic poliomyelitis, are replaced by vaccine viruses. The larger the number of children immunized and the larger the size of the area covered, the higher the likelihood of the replacement of the wild viruses. Also, all pockets of 'high-risk' in the PHC area or the district should be covered, otherwise foci of infection will remain with the potential of spread to the areas where the 'mop-up' rounds have been successfully conducted. The mop-up rounds are in addition to, and not a substitute to routine immunization services.

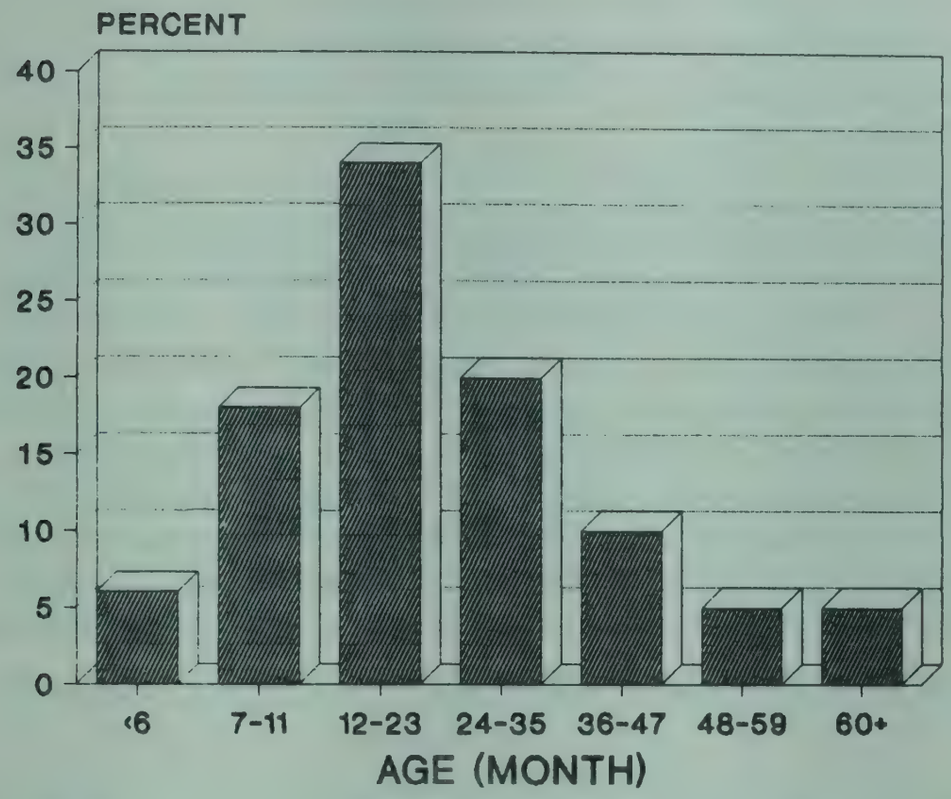
5. Since the purpose of these rounds is to replace the wild polio viruses with the vaccine virus, the effectiveness of the rounds increases if these are conducted in the low transmission season (months during which the number of reported cases is minimum). In India, the number of cases start increasing from May to October, with a peak in July - August. The mop-up rounds should be organized before or after the seasonal peak during the period October to April. The organization of the rounds, therefore, require careful

planning, mobilization of additional resources, enhancing IEC activities and promoting community support. Experience of any previous rounds should be taken to eliminate problems encountered earlier. Planning of the rounds should start at least three months in advance. Poorly planned and implemented 'mop-up' rounds have little epidemiological impact and are a wasteful expenditure of scarce resources.



6. The median age for poliomyelitis in the country is 18 months. In other words, in half the cases, the onset of paralysis occurs at or before the age of 18 months. The course of three doses of OPV should be completed as early as possible, preferably starting at 6 weeks and completing at 14 weeks, before the child is exposed to the risk of infection.

AGE AT ONSET OF PARALYSIS



7. OPV vials have pre-sterilized plastic dispensers (droppers). These are attached to the vial after it is opened. While distributing vaccines, it must be ensured that OPV vaccine droppers are also included. The child should receive the correct dose of vaccine by using the dispensers provided by the manufacturers. OPV vials should be carried to the field in a proper cold chain. During the session, the vials should be kept on an ice pack.

STRATEGIES

- Reach and sustain coverage levels >85%
- Identify 'at risk' pockets
- Conduct 'mop-up' rounds in low transmission period
- Strengthen surveillance
  - Ensure timely and complete reporting of cases of acute flaccid paralysis
  - Improve clinical diagnosis to differentiate polio from non-polio cases
  - 60 day follow up of suspect polio cases to confirm diagnosis
  - Virus isolation to confirm diagnosis

8. Surveillance is critical to achieving eradication of poliomyelitis. Reliable surveillance data are required to identify high-risk areas and to document impact. All sources of data collection should be used including hospitals and reporting of suspect cases by the peripheral health staff. Notification should include all cases of acute flaccid paralysis so that no case of poliomyelitis is missed.

9. Due to the large size of the country, the goal of polio eradication has been phased with polio-free zones being extended every year. In Himachal Pradesh, Haryana, Karnataka, Kerala, Maharashtra, Mizoram, Punjab, Tamil Nadu, Chandigarh, Goa and Pondicherry, with a combined population of over 250 million, the aim is to achieve zero cases of poliomyelitis by the end of 1994. These states have overall high levels of immunization coverage, significant decline in the incidence of poliomyelitis, a reliable surveillance system and the capacity to undertake supplementary activities required for polio eradication. The other states and union territories have similar targets by the end of 1996 and 1997, respectively. In these states, the number of polio-free districts can be progressively increased.

10. **The following factors are strategically important for eradication efforts in India:**

- The pool of susceptible children in the country is very large. The overall reported immunization coverage levels with the third of dose of OPV is around 85%. The 3.75 million children who remain unimmunized every year maintain foci of infection and continued transmission of the polio viruses. It is important that the immunization coverage levels are further increased to reduce the pool of susceptible children.
- There are large number of metropolitan cities in India with a high in-migration, resulting in a number of densely populated slums with poor sanitary conditions. These conditions are favourable for polio virus transmission. The children are also likely to be infected much earlier than the average age-groups. Urban slums require special attention.
- The movement of the people between districts and states is high. People from the disadvantaged sections of some states (likely to be with less than average immunization coverage levels) often seek short-term work in other states. This facilitates the spread of the polio viruses over large distances and potential contamination of a polio-free zone. All states and districts must review action plans and take adequate measures to reduce transmission of polio viruses by increasing immunization coverage levels in infants and by initiating supplementary activities in the 'high-risk' pockets to eliminate foci of infection.

11. **A summary of the strategies for polio eradication are:**

- Sustain high levels of immunization coverage of at least 85% in infants with three doses of oral polio vaccine (OPV). Initiate the first dose of OPV at 6 weeks of age or soon as possible, thereafter, and to complete the subsequent doses at monthly intervals.

- Supplementary activities of additional rounds of OPV administration in pockets at 'high risk'. During the additional rounds all children under three years of age are given two doses of OPV, at monthly intervals, irrespective of previous immunization status. The purpose is to reduce the circulation of the wild polio viruses in these pockets. The high risk pockets are subcentre areas/blocks/wards which have either reported a cluster of cases or have consistently reported cases over the last two to three years. The rounds are organized during the low transmission period from October to December or in March and April prior to the expected seasonal increase in cases.

- Organization of national immunization days to increase immunization levels in areas with low coverage. All vaccines are available at the special immunization sessions organized on the first sundays in October, November and December. The national immunization days are organized with the support of voluntary agencies and professional bodies. Particular attention is given to urban slums and other pockets with low immunization coverage.

- Outbreak containment measures following the report of a case in the acute phase of the disease. Even a single case is treated as an outbreak and preventive measures are initiated, usually within 48 hours of notification of the case. The complete and timely reporting of cases of poliomyelitis is an important element for polio eradication. The containment measures are effective if conducted as early as possible after the onset of paralysis since the polio viruses can spread fast over large distances. Containment measures in the area of residence of the case are, therefore, not recommended if the period after onset of paralysis is more than 14 days. **Other investigations and follow-up action for an outbreak should, however, be conducted**. Such investigations are necessary to take corrective measures to improve immunization services. It also alerts the community about the serious intent for achieving the goal of polio eradication.

- Reporting of cases of Acute Flaccid Paralysis (AFP) has been made mandatory and line lists of all reported cases must be maintained. Active surveillance through the peripheral health staff must be started. Line list should be maintained for all reported cases. The case should be clinically examined 60 days after onset of paralysis as cases of AFP of non-polio etiology are expected to recover by this time and have no residual paralysis, unlike poliomyelitis.

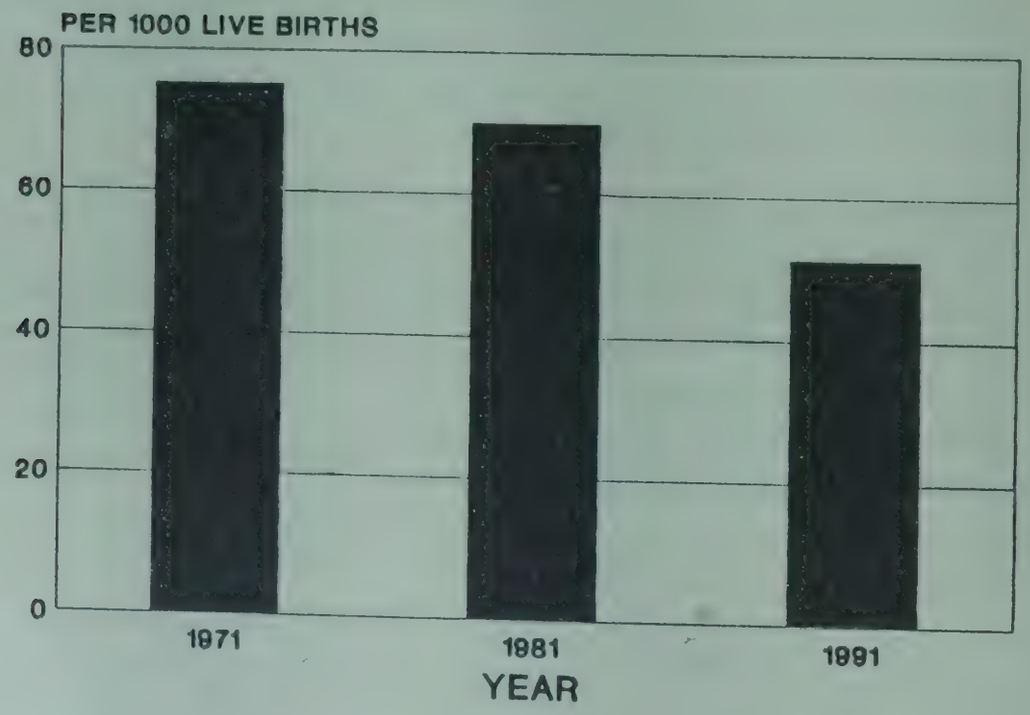
III. NEONATAL TETANUS ELIMINATION

1. Prior to the national immunization programme, an estimated 0.35 million children died annually due to neonatal tetanus. The baseline surveys conducted in 1981 confirmed that 25 to 33% of neonatal deaths were due to tetanus. The problem of neonatal tetanus is usually under-estimated as the children die within a few days of birth often without being brought for treatment. Unless there is active surveillance, deaths due to neonatal tetanus may not be recorded or reported.

2. Two doses of TT vaccine, at an interval of one month, provide adequate protection against tetanus. If there is history of previous immunization, one dose (booster) is sufficient. However, in case of any doubt, two doses should be given. Pregnant women are immunized to protect them and the newborns against tetanus. Immunization should not be delayed. The first dose is given at the first contact during pregnancy and the second after an interval of one month. The last dose should be given at least one month before the expected date of delivery.

3. In 1993-94, 81% of the pregnant women were immunized, although there was a wide variation between states and within districts. 44% of the deliveries in 1990 were either institutional or by trained personnel, while 56% were conducted by untrained personnel. In Rajasthan, Madhya Pradesh, Bihar, Orissa, Assam and Uttar Pradesh, more than 70% of the deliveries were by untrained personnel.

NEONATAL MORTALITY RATE



4. As a result of the increase in the TT immunization coverage levels, neonatal tetanus has been eliminated in large parts of the country and the incidence reduced in other parts. However, neonatal tetanus still continues to be a public health problem in the states where the proportion of unattended deliveries is high and immunization coverage levels low. The reduction in the incidence of neonatal tetanus is reflected by the fall in the neonatal mortality rate by 26.7% from 69.9 per 1000 live births in 1981 to 51.1 in 1991.

5. Tetanus occurs when tetanus spores come in contact with an open wound. The risks are high at the time of delivery if practices are unhygienic and the women is unimmunized. The use of the five clean practices greatly reduces the risks of tetanus (maternal and neonatal) as well as puerperal sepsis. The newborns are at added risk if the umbilical cord is cut with an unclean instrument.

FIVE CLEAN PRACTICES

- ❖ Clean surface for delivery
- ❖ Clean hands of the attendant
- ❖ New blade for cutting the cord
- ❖ Clean tie for the cord
- ❖ No applicant on the cord stump

6. The clean practices are within the means of all families. If the pregnant woman knows and understands the importance of the practices for herself and her child, she can **INSIST AND ENSURE** that whoever assists her at the time of delivery, washes her hands thoroughly with soap and water, uses a new (unopened) blade for cutting the cords, use clean ties for the cord and does not apply anything on the cord stump. Funds have been allocated for the purchase of a simple disposable delivery kit (DDK) consisting of a new blade, two cord ties and two pieces of gauze and a piece of soap. The DDK should be given to the pregnant woman during antenatal clinic and she should be advised about clean delivery practices.

7. A case of neonatal tetanus is a failure of the system to provide TT immunization, ensure delivery practices by trained personnel and disseminate relevant information to the family and the community about clean delivery practices. If there is a case of neonatal tetanus, status of the immunization programme and delivery practices in the area should be assessed with the highest priority. Besides improving immunization coverage levels, training of dais should taken up in the area. In areas where the proportion of domiciliary deliveries by untrained personnel is still high, IEC activities should be stepped up and DDK supplied to the pregnant women.

8. Even a single case of neonatal tetanus should trigger follow-up action to

prevent cases in the future. Areas from where cases of neonatal tetanus have been reported should be spot-mapped. The quality of programme interventions in these areas should be reviewed separately by the supervisory staff.

FOLLOW-UP ACTION TO BE TAKEN IN AN AREA WITH A CASE OF NNT

- ❖ Improve TT immunization coverage
- ❖ Arrange dai training programme
- ❖ Supply disposable delivery kits
- ❖ Intensify IEC activities
- ❖ Improve surveillance

9. Since TT immunization is very effective and clean delivery practices will reduce risks of neonatal tetanus substantially, it is potentially feasible to eliminate neonatal tetanus within a relatively short period of time. All PHCs and districts should aim at zero cases of neonatal tetanus. The definition of neonatal tetanus (NNT) elimination is a rate of less than one case per 10,000 live births. Since the tetanus spores are widespread in the environment TT immunization and clean delivery practices must be continued indefinitely.

10. **The strategies for neonatal tetanus elimination are:**

- ☐ Increase and sustain high coverage levels with two doses or a booster dose of TT in pregnant women.
- ☐ Increase proportion of deliveries by trained personnel; intensify dai training programme.
- ☐ Supply disposable delivery kits to ensure clean practices for domiciliary deliveries.
- ☐ Implement essential newborn care, including cord care, to reduce risks of neonatal tetanus.
- ☐ Strengthen surveillance system and undertake follow-up action in areas from where cases are reported.
- ☐ Continue IEC activities in the community with special focus in areas from where cases have been reported and in areas where the proportion of deliveries by untrained personnel is high.

IV. CONTROL OF MEASLES

1. All children are susceptible to measles infection unless protected by immunization. Measles has a wide range of clinical severity. In malnourished children, case fatality rates of post-measles complications are high if appropriate treatment is not started early after the onset of symptoms. Deaths due to measles are preventable by immunization between 9 to 12 months of age and by appropriate and early treatment of post-measles complications.

2. One dose of measles vaccine provides life-long immunity. Since the median age for measles infection is around 24 months of age, it is important that children receive measles vaccine at 9 months of age or as soon as possible thereafter and are immunized before they are exposed to the risk of infection. Coverage with measles vaccine has increased from 1.3% in 1985-86 to 86.9% in 1993-94. The rapid increase in measles immunization coverage levels has saved many lives. However, each year about 15% of the 25 million infants or 3.75 million children remain unimmunized and are potentially at risk of measles infection.

3. As a result of the vaccination programme, the reported incidence of measles has declined substantially. The reported average annual number of 179,000 cases during the period 1985-89 has declined to around 80,766 during the period 1990-93. According to provisional data for 1993, 63409 cases have been reported. A 75% decline in the incidence of measles has been recorded in 1993 as compared to 252940 cases reported in 1987.

4. Measles immunization coverage levels, although relatively high, are not uniform with wide variations between the states and the districts. Within districts, the unimmunized children are clustered in pockets of 'high-risk' such as urban slums, peri-urban areas and remote, difficult to approach rural areas. Some districts are yet to reach high coverage levels. These areas are at risk of measles outbreaks. Although reports of large outbreaks of measles are becoming increasingly rare, several relatively small outbreaks were reported in the last few years, largely in the tribal and remote areas. Case fatality rates are generally much higher during outbreaks than the average rates due to relative inaccessibility to health facilities and other socio-economic factors. Anticipatory action taken in the high risk pockets can minimize the risks of outbreaks and reduce mortality rates. Early identification of outbreaks is also important in controlling the spread of the outbreak and in minimizing mortality rates.

5. The treatment facilities and the health staff must immediately report any sudden increase in cases. Even a single case from far-flung, difficult to approach and tribal areas should be treated as an outbreak and necessary investigations and follow-action must be initiated immediately to prevent deaths due to measles.

6. The common complications of measles are diarrhoea and pneumonia. Timely and appropriate management of cases of diarrhoea and pneumonia will reduce case fatality rates and save many lives. It is important that community is made aware of the importance of increased fluid intake and continued feeding during episodes of diarrhoea and of the signs of pneumonia (increased respiratory rate and chest indrawing) for seeking immediate medical help. Heath educational activities must be started before an outbreak has occurred. Precautionary measures taken in anticipation of outbreaks in high risk pockets will help to minimize measles mortality rates.

7. Since a single dose of measles vaccine is effective in controlling measles and since the control of measles will have a significant impact on the infant and child mortality rates, all countries, including India, have adopted the goal of 90% reduction of measles incidence and 95% reduction of measles mortality by 1995.

8. Measles leads to malnutrition in children and depletes vitamin A reserves. The control of measles will have a positive impact on the nutritional status. It will also reduce the episodes of diarrhoea and pneumonia in young children.

9. Encephalitis can occur between the second and sixth day after the onset of rash. Encephalopathy can also develop in children with severe post-measles pneumonia due to acute circulatory disturbances and hypoxemia. Although, reliable data in the country is not available, according to some reports a CNS complication rate of 50 to 400 per 100,000 cases of measles can be expected.

10. **The strategies for measles control are:**

- Increase and sustain high levels of immunization coverage in children between 9 to 12 months of age with one dose of measles vaccine.
- Identify high risk pockets and intensify immunization coverage in these pockets on priority to prevent outbreaks of measles.
- Strengthen surveillance system for vaccine preventable diseases, including measles for identification of high risk pockets, early identification of outbreaks and to document impact of services
- Ensure timely and appropriate treatment of complications following measles to prevent deaths.
- Continue IEC activities to promote measles immunization at the right age and to create awareness about what families should do if a child has diarrhoea or pneumonia following an episode of measles.

V. SEVERE ADVERSE EVENTS FOLLOWING IMMUNIZATION

1. The vaccines used under the Immunization Programme are safe and effective. This is documented by the experience of using nearly 650 million doses of these vaccines annually in the country for a decade and similar experience worldwide. However, just as no vaccine is 100% effective, none is entirely without risk and severe, life-threatening adverse events following immunization can occur but these are extremely rare.

2. It is important that the adverse events are recorded and investigated as these can influence public acceptance of immunization services. Immediate response from the concerned health authorities will convince the community of the concern for the lives of their children and for maintaining high quality of services. A reliable surveillance system will also document the low incidence of such events.

3. **Among the recorded and documented severe events following immunization which can lead to death or severe life-long sequelae are:**

   - Anaphylactic shock
   - CNS complications due to pertussis vaccine
     - Some studies in the UK suggested a rate of a serious acute neurological illness at a rate of 1 in 140,000 DPT injections and permanent damage in 1 in 330,000 injections. More recent studies have questioned these findings and have failed to implicate DPT vaccine. If DPT is causally associated with permanent neurological damage, it is a much rarer event than previous estimates indicated.
     - Similar syndromes are also seen in non-immunized children, often making it difficult to distinguish between vaccine induced and a coincidental event.
     - The CNS complication rate of pertussis are estimated to be 90 to 4000 per 100,000 cases. Comparable data in the country are not available. The underlying cause of CNS complications in pertussis are related to asphyxia from severe paroxysms, petechial haemorrhages, massive subarachnoid bleeding and diffuse encephalopathy.
   - Paralysis caused by OPV
     - The risk of vaccine associated paralysis is 1 per 1.2 million children immunized.
     - In polio-endemic areas, classification of vaccine-associated illness is not possible.

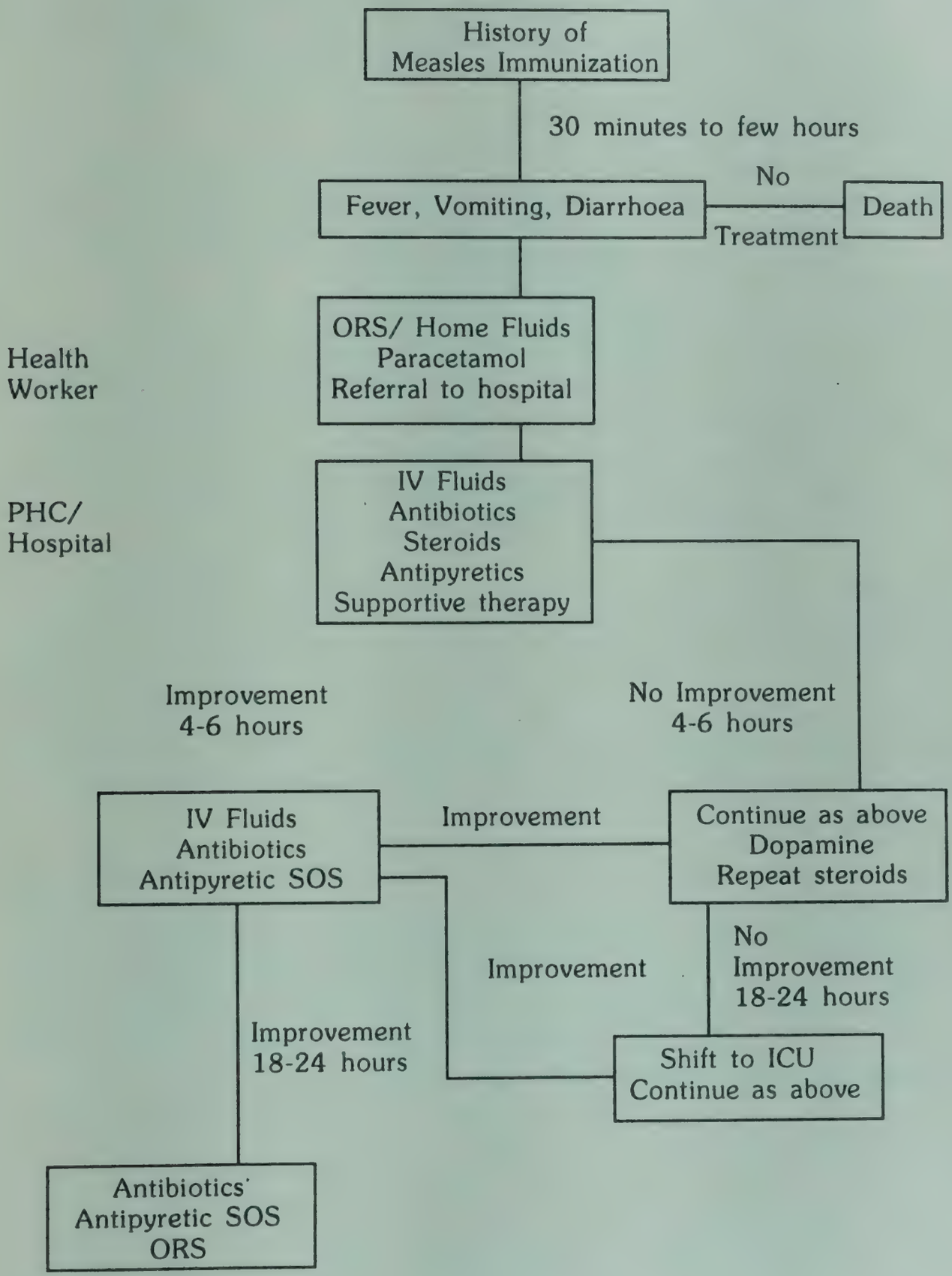
4. **Other reactions which can influence public acceptance of services, but are not life threatening are:**

   - Lymphadenitis following BCG vaccination
     - BCG lymphadenitis is reported in 1 to 2% of immunized children. If the rates increase, investigations should be conducted. Among the possible causes are incorrect dilution of the vaccine, change in the manufacturer of the vaccine and incorrect administration of the vaccine due to a change in the vaccinator.
     - Parents should be reassured that the lymphadenitis will clear by itself and that it is not painful to the child. It will not cause tuberculosis. No medication is necessary.

5. Serious life threatening reactions can occur if the vaccines are not stored, transported and administered according to the guidelines. These are totally preventable and reflect poor quality of services.

   - Bacterial abscess due to the use of unsterile syringes and needles and reuse of syringes and needles for more than one injection.
     - Bacterial abscesses must be treated. Abscesses can be fatal in young children if not treated.
     - Bacterial abscesses indicate poor quality of services. Corrective measures must be taken immediately.
   - Toxic shock syndrome (TSS) following the administration of contaminated measles vaccine due to the use of unsterile syringes and needles used to draw out the vaccine from the vial or reuse of measles vaccine vial for more than one session on the same or subsequent days.
     - The symptoms of TSS are typical. Severe watery diarrhoea, vomiting and high fever are reported within a few hours of measles vaccine administration. There are usually more than one case as all children vaccinated from the contaminated vial will be affected. TSS occurs when the vial is contaminated with *Staphylococcus aureus*.
     - The disease progresses to hypotensive shock and death within 48 hours. Case fatality rates are high.
     - TSS is an emergency and no time should be lost in taking the patient(s) to a district hospital which can look after severely ill children and provide supportive care. If the child is brought first to a PHC, a broad spectrum antibiotic should be given and an intravenous drip started before referral of the case **by the quickest mode of transportation**. The recommended steps for the management of a case of TSS is given in the figure:

MANAGEMENT OF TSS
Flow Chart



MONITOR VITAL SIGNS,
URINE OUTPUT SHOULD NOT REDUCE BELOW 7 ML/KG/HOUR

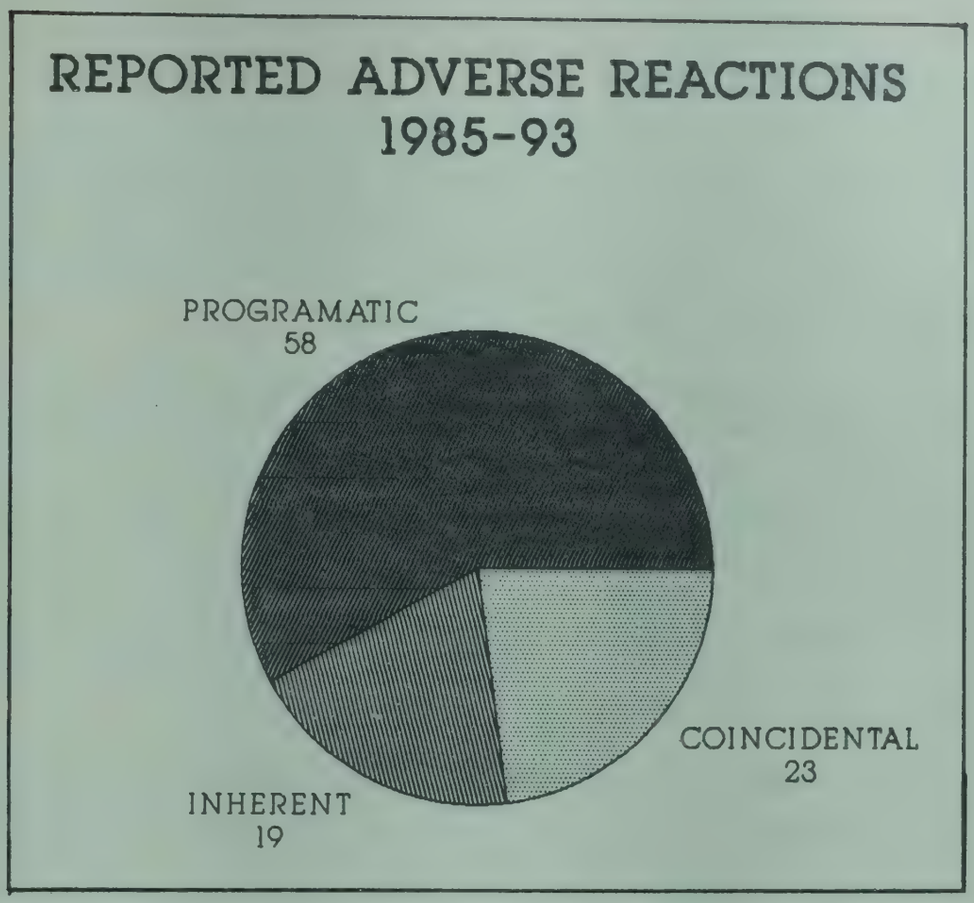
- TSS reflects extremely poor quality of services, an utter disregard of the guidelines and lack of supervision. **Deaths due to TSS are unpardonable and the concerned staff and supervisory officers must be held responsible**. Follow-up action should include review of the quality of the immunization services in other health centres in the district to rule out poor quality in these centres.

- Accidental use of another drug
  - Other drugs must not be stored with vaccines for which separate refrigerators have been provided. The accidental use of a drug in place of a vaccine or diluent has been recorded, both in India as well as in other countries.

- Traumatic neuritis
  - Paralysis due to injury of the sciatic nerve by improper injections of vaccines (and other drugs) can occur. Traumatic neuritis can be confused with poliomyelitis since paralysis is unilateral and there may be history of fever (for which the drug was administered). **Intramuscular injection of vaccines (DPT) should be given in the upper thigh and not in the gluteal region.**

6. Since vaccines are given at an age when infections are common and morbidity and mortality rates higher than in the other age-groups, it is not uncommon for a coincidental event to be attributed to immunization if the vaccines were given on the same day or the previous day. Such incidents can include events where history of preceding illness can be obtained. Some events occur as an acute episode and require investigations by experienced paediatricians and other experts. Such events include death by aspiration and Sudden infant death syndrome.

7. The surveillance of severe adverse events following immunization was started in 1986. Reported deaths following immunization are required to be investigated within 48 hours. Each state has constituted an expert standing committee of an epidemiologist, a paediatrician and a microbiologist on call to ensure prompt and thorough investigation of severe adverse events. 166 deaths have been investigated during the period 1985 to 1993, of which 58% were due to programmatic errors.



8. **The following measures should be taken to minimize risks of adverse events due to programmatic errors:**

   - Procedures for sterilization of syringes and needles should be scrupulously followed and monitored. Steam sterilization should be given preference over boiling.
   - A single, sterile syringe and a single, sterile needle should be used for every injection.
   - Measles vaccine should be used **within 4 hours** of reconstitution. An opened vial of measles vaccines should **NEVER** be reused.
   - Diluent for BCG and measles vaccine should be kept separate from other potentially harmful injectable drugs.
   - Training programmes for all categories of personnel should receive the highest priority to ensure high quality of services.
   - Reporting of abscesses by health workers in their areas should be made compulsory.
   - Field monitoring of services should be regular and any deficiencies should be noted and corrected in a timely manner.

9. Other events can also occur following immunization but are relatively rare. Uniform case definitions of adverse events following immunization help in the investigation of these events and facilitate appropriate management of cases.

- **Specific Local Reactions**
  - **Bacterial site abscess** : Occurrence of draining urgent fluid-filled inflammatory lesion or fluctuant fluid-filled, distinctly inflammatory lesion at the site of injection within 72 hours of immunization, with or without fever; may be supported by positive Gram stain, culture or finding of neutrophil predominance.
  - **Sterile site abscess** : Occurrence of draining fluid-filled lesion or fluctuant fluid-filled lesion at the site of injection within 72 hours of immunization, with minimal inflammation, and not associated with fever; may be supported by negative Gram stain, negative culture for routine organisms, or finding of macrophage predominance.
  - **Moderate local reaction** : Non-fluctuant swelling and redness of approximately 3 cm (width of two adult fingers) to less than 10 cm (width of adult fist) at the site of injection.
  - **Severe local reaction** : Non-fluctuant swelling and redness of approximately 10 cm or larger (width of adult fist) at the site of injection.
  - **Massive local reaction** : Severe local reaction with extension of swelling past the closest joint (e.g., knee).
  - **Local ulcer** : Localized circumscribed inflammatory denuding of the skin at the site of BCG immunization.

- **Relative Specific Syndromes**
  - **Anaphylaxis** : Acute decompensation (within 8 hours, generally within 1 hour) of circulatory system with indications of poor peripheral blood flow and associated with immediate alterations in the vaccinee's level of consciousness or acute bronchospasm or laryngospasm or laryngeal edema leading to acute respiratory distress.
  - **Hypotensive-hyporesponsive episodes** : Evidence of acute paleness, transient decreased level or loss of consciousness, decrease or loss of muscle tone within 12 hours of DPT injection.
  - **Excessive inconsolable crying** following DPT immunization.
  - **BCG lymphadenitis** : Occurrence of any of the following by examination and/or history between 2 and 6 months after receipt of BCG immunization: Multiple axillary lymph nodes of 1.5 cm (one adult finger width) or larger in the largest axis or at least one node of 3.0 cm (two adult finger widths) or larger in the largest axis.
  - **Suppurative BCG lymphadenitis** : BCG lymphadenitis when associated with one of the following (i) fluctuant upon palpation, (ii) fixed to the skin; or (iii) associated with a draining sinus.

- **Non-specific Systemic Events**
  - **Encephalopathy** : Occurrence of any two of the following by examination and/or distinct clinical history within 72 hours of immunization: (i) seizure; (ii) severe alteration in the level of consciousness lasting for one day or more; or (iii) distinct change in personality or behaviour lasting one day or more.
  - **Encephalitis** : Encephalopathy with cerebrospinal fluid pleocytosis of more than 10 cells/mm^3.

- **Motor Seizure**
  - **Simple febrile seizure** : Seizure or series of seizures accompanied by fever upon examination or by history, lasting less than accompanied by focal neurological signs or symptoms in a child between 6 months and 6 years of age.
  - **Complex seizure with fever** : Seizure or series of seizures accompanied by fever upon examination or by history, lasting approximately 15 minutes duration or longer or accompanied by focal neurological signs or symptoms, or first seizure with fever in a child less than 6 months of age or more than 6 years of age.
  - **Seizure without fever** : All motor seizure occurring without apparent fever.
  - **Focal seizure** : All focal seizures, with or without generalization, or any seizure accompanied by focal findings, such as unilateral paralysis in the post-ictal period.
  - **Fever** : High grade fever (>39°C).

10. All reported deaths and other severe events requiring hospitalization are notified to the State MCH Officer and to the Ministry of Health and Family Welfare. Copies of the investigation and action taken reports must also be submitted for compilation at national level and for dissemination to programme officers in other states.

VI. THE COLD CHAIN SYSTEM

1. INTRODUCTION

1.1 The cold chain is a system of transporting and storing vaccines at recommended temperatures from the manufacturer to the point of use. The cold chain is essential as vaccines lose their potency if exposed to temperatures above 8°C. Once the vaccines lose their potency, it cannot be restored even if these are put back in the refrigerator.

1.2 The loss of potency is dependent on the temperature and the duration of exposure. At high temperatures, even short periods of exposure can be detrimental to the vaccines. Vaccines are also sensitive to direct sunlight.

1.3 During the transportation of vaccines there are a large number of levels and personnel involved in the cold chain system. A break in the chain at any level will affect the vaccines.

1.4 Vaccines also have a limited shelf life and must be used within the expiry date. Large stocks should not be maintained in the peripheral health facilities and the principle of first-in, first-out' should be followed.

1.5 It is essential that the equipment are handled properly and the preventive maintenance is undertaken from time to time. Equipment which are used properly, function for a longer time. However, in anticipation of a breakdown of the equipments, contingency arrangements for storing vaccines must be made.

1.6 Since the vaccines must be kept at temperatures between 2 to 8°C (or below for some vaccines), the proper storage, handling and transportation of the vaccines is critical for the success of the immunization programme.

2. VACCINE REQUIREMENT

2.1 Estimation of vaccine requirement at various level is essential for proper implementation of the programme. This will help to indent the right quantity so that there is no over or under stocking and that no session is cancelled due to shortage of vaccines. While calculating the requirement following factors are to be considered:

- ☐ number of beneficiaries
- ☐ number of doses of each vaccine
- ☐ wastage multiplication factor
- ☐ number of sessions

For example, in a PHC with a population of 30,000, birth rate of 29/1000 population, estimated beneficiaries would be:

Pregnant women

$$30{,}000 \times \frac{29}{1000} + 10\% \text{ (pregnancy wastage)} = 957$$

Infants born = 870

Infants alive at 1 year (92.i% of born = 801

OPV/DPT doses to be administered (4 doses to be given to each child) 801 x 4 = 3204

OPV/DPT doses required (Wastage multiplication factor 1.33) 3204 X 1.33 = 4261

BCG/ Measles doses to be administered = 801

BCG/Measles doses required (Wastage Multiplication factor =2) = 1602

The vaccines are supplied in 10 or 20 doses vials or ampoule. To calculate the number of vials required, number of doses are divided by 10 or 20 and rounded off to the next 10 or 20 as per the number of doses per vial. The quantities thus calculated would be for the whole year.

However, the requirement would increase as all sessions are to be provided with vials of each antigens.

For example, if there are 6 subcentres in a PHC of 30,000 population then it would be expected that per month there will be 4 out reach sessions for each subcentre and PHC would organise 4 fixed session. Thus the total number of 28 sessions are to be held in the PHC area per month. Number of sessions would also increase if there are other institutions in the area.

A simple ready reckoner that would help to estimate the monthly requirement of vaccine for out reach session is give below:

Sl. No.	Population	Community	Monthly target		Monthly Vaccine Requirement in vials/ ampoule				
			Pregnant women	Infants	BCG	OPV	DPT	Measles	TT
1.	1000	Village/Ward	3	3	1	1	2	1	1
2.	2000	do	7	6	1	2	3	1	2
3.	3000	do	10	9	1	3	4	2	3
4.	4000	do	14	12	1	3	5	2	3
5.	5000	do	17	15	1	4	7	2	4

Calculation for vaccine requirement is to be done on the basis of the number of sessions planned for each month. Additional OPV doses for containment vaccinations and mop-up rounds would also be needed. These have to be calculated on the basis of under 3 population and area to be covered.

3. MONITORING VACCINE SUPPLY AND UTILIZATION

3.1 It is essential that vaccine issue is regularly monitored to see that the vaccines are issued on the day of session and that the vaccines issued tally with the estimated number of beneficiaries likely to attend the session. Monitoring of vaccine utilization will help to assess service delivery.

FOLLOW FIRST-IN FIRST-OUT RULE
Vaccines received earlier or with short expiry date should be used first

3.2 Vaccine utilization should be periodically tallied with the number of children immunized. If a subcentre reports high vaccine utilization rates, further investigation should be done to rule out:

- ☐ false reporting of immunization performance
- ☐ reuse of opened vials of vaccines
- ☐ duplication of reported performance

3.3 Vaccines should be issued only in cold chain.

3.4 Vaccine stock and issue register must be kept up to date.

EXERCISE A

As the Medical Officer in-charge of a CHC catering to a population of 100,000, you are responsible for providing 100% immunization. There are 3 PHCs and 20 sub-centres in your area. It is estimated that there will be 3200 pregnant women and 3,000 infants in your area. There are in all 115 villages out of which 90 villages have a population of 1000 or more.

Method No. 1

Calculate the vaccine requirement in a year according to the number of expected beneficiaries alone. (The expected number in case of DPT/OPV will include 3 doses of primary immunization and 1 dose of booster).

Consider (20 dose vials for OPV and BCG and 10 dose vials for other vaccines)

Vaccine	DPT	OPV	BCG	MEASLES	TT
No of Vials					

4. THE COLD CHAIN EQUIPMENT

There are various equipments which are used for storing and transportation of vaccines.

4.1 Walk-in-coolers (WIC)

The Walk-in-coolers are to store vaccines for 3 months and they serve a region of 4-5 districts. It is important to know the location of WIC of your region so that in an emergency you may be able to collect supplies from them.

4.2 Deep Freezers (300 ltr) and Ice Lined Refrigerators (ILRs 300/240 ltr) Capacity

These have been supplied to all districts and at WIC locations to store vaccines. The Deep Freezers are used for making Ice packs and to store OPV and measles vaccines.

4.3 Small Deep Freezers and ILRs of 140 litre Capacity

One set of (Deep Freezer and ILR) has been provided to PHCs, Urban Family Welfare Centres and Post-partum Centres.

The Deep Freezers are to prepare frozen Ice Packs which are used in cold boxes, vaccine carriers for transportation of vaccines and during the sessions.

All vaccines at PHC level are stored in the ILR. Vaccines like TT, DPT, DT and BCG are kept in the basket provided with the ILR. These vaccines are never to be kept on the floor of the ILR as they may freeze and get damaged. The Dial Thermometer should be kept in the ILR and temperature should be recorded twice a day. At the time of defrosting the vaccines are to be shifted to the cold boxes in which required numbers of frozen Ice Packs have been already placed. In case of equipment failure or electric supply failure transfer the vaccines to the cold boxes and shift them to alternate vaccine storage.

Dos and DONTs for use of ILR/Freezer

Dos

- Keep the equipment in cool room away from direct sunlight and atleast 10 cms away from the wall
- Keep the equipment level
- Fix permanent electric connection through voltage stabilizer
- Keep vaccines neatly with space between the stacks for circulation of air
- Keep the equipments locked and open only when necessary
- Defrost periodically
- Supervise the temperature record

- Take immediate action if the equipments fail
- Vaccines if kept in cartons, make holes on the sides cartons for cold air to circulate

DONTs

- Do not keep any object on these equipments
- Do not store any other drug
- Do not open unless necessary
- Do not keep food or drinking water in them
- Do not keep more than one month's requirements at PHC level and 3 months requirement at district level.
- Do not keep date expired vaccines

RECORDING AND MONITORING OF STORAGE TEMPERATURE

Temperature of the ILR and the Deep Freezers should be recorded twice a day. This is done to ensure that at no time the temperature has risen above 8°C of has fallen below 2°C. Therefore it is necessary to adjust the thermostat in different seasons so that the temperature is maintained within prescribed limits.

4.4 Cold Boxes

Adequate numbers of Cold Boxes have been supplied to all peripheral centres. These are mainly to be used for transportation of vaccines. In emergency they can also be used to store vaccines. Before the vaccines are placed in the cold boxes fully frozen ice packs should be placed at the bottom and sides. The vaccines should be placed in cartons or polythene bags and then placed in the cold box. Cover the vaccines with a layer of fully frozen ice packs and close the cold box. The vials of DPT, DT and TT vaccines should not be placed in direct contact with the frozen ice packs.

4.5 Vaccine Carriers

Vaccine Carriers are used to carry small quantities of vaccines (16-20 vials) for the outreach sessions. 4 fully frozen Ice packs are to be used for lining the sides and the carrier must be closed tightly. The vials of DPT, DT and TT vaccines should not be placed in direct contact with the frozen ice packs.

4.6 Day Carriers

Day carriers are used for carrying small quantities of vaccines (6-8 vials) to a near by session. Two fully frozen ice packs are to be used. Day carriers are can maintain the temperature for for a few hours only and hence vaccines in day carrier should be only issued on the day of immunization.

4.7 Ice Packs

Ice packs are used to line the sides of cold boxes, vaccine carriers and day carriers. The Ice packs contain water and no salt should be added to it. The water should be filled upto the level marked on the side. If there is any leakage such ice packs should be discarded. The ice packs should be prepared in the deep freezer and only fully frozen ice packs should only be used. The ice packs are to be placed vertically on the floor of the Deep Freezer and at a time not more than 20-24 ice packs should be prepared. Once the ice packs are fully frozen, fresh set of ice packs can be prepared.

Steps to be Followed to Pack Vaccines in Cold Box/Carriers

- Take out cold Box/ carriers and confirm that there are no cracks.
- Clean the cold box/carrier
- Take out required number of fully frozen ice packs from the deep freezer and wipe them dry.
- Place the ice packs in the cold box/carrier and wait for few minutes for temperature to stabilize
- Put the vaccines along with diluents in a carton/polythene bag and place them in the box/carrier
- Place packing material between vials containing TT, DPT and DT and ice packs so that these vaccines do not get frozen
- Secure the lid tightly
- Do not keep the box/carrier in sunlight or near a source of heat.
- Do not keep heavy object on them or sit on them.
- Open the only when required

4.8 Automatic Voltage Stabilizers-1KVA

One set of ILR and Deep Freezer (140 Ltr) is to be connected through the voltage stabilizer. It provides an output voltage is between 210-230 volts. If the input voltage goes below 150 or above 280 volts, the stabilizer automatically cut off the supply. This prevents damage to the equipments.

EQUIPMENT SHOULD BE CONNECTED THROUGH STABILIZER AND NOT DIRECTLY WITH THE POWER SUPPLY

5. MAINTENANCE OF EQUIPMENTS

The Cold Chain Equipment are vital for maintaining the potency of the vaccines supplied under the programme. In order to avoid breakdown of these equipments, it is necessary to undertake preventive maintenance of the equipments. The responsibility to handle and maintain the equipments should be given to a dependable person. The District MCH Officer may also send the refrigerator mechanic every month to the PHC along with the vaccine supply to check the equipments and to do the preventive maintenance.

5.1 Checklist for Preventive Maintenance

A External	
1 The exterior is clean	
2 It is firm on the floor	
3 It is properly levelled	
4 Its sides are atleast 10 cm away from walls	
5 It is away from direct sunlight	
6 Room is well ventilated	
7 It is opened only when necessary	
B Internal	
1 Lid seals properly without gap	
2 Lid seal is clean	
3 Ice lining tubes/ice packs are in proper position	
4 Ice lining tubes/ice packs filled water to proper level	
5 Thickness of frost formation is less than 6 mm	
6 Vaccines are neatly placed with space for air circulation	
7 DPT,TT and DT are kept in the basket in the ILR and not touching the cooling surface	
8 Thermometer has been kept among the vaccines	
9 Temperature is recorded twice a day	
C Technical	
1 Temperature within prescribed limit (if not, set the thermostat)	
2 Voltage stabilizer is working properly and equipments are connected through it	
3 Plug of the voltage stabilizer is fitted properly to the power line	
4 Connection of equipments to voltage stabilizer are not lose	
5 There is no abnormal noise	
6 Compressor mounting bolts are tight	

5.2 Defrosting and Cleaning

The temperature in the ILR/Deep Freezer can rise if there is a thick layer of ice on the walls or at the bottom. Therefore periodically defrosting should be done if the layer of frost is more than 6mm.

- ☐ Vaccines need to be shifted to cold boxes which has already made ready by lining the walls and bottom with frozen ice packs.
- ☐ Incase of deep freezer shift the frozen ice packs to cold box.

- Switch off the power supply and remove the plug.
- Keep the lid open and allow the frost to melt.
- Never use any sharp object to remove the frost.
- Only warm water can be used to speed up defrosting.
- Wash inside and outside with warm water and mild detergent
- Allow the parts to dry completely.
- Connect the power supply.
- Turn the thermostat for maximum cooling. Observe the temperature and reset the thermostat.

The lid of the ILR/Freezer may be stuck immediately after closer for a few minutes due to negative pressure. Do not force open the lid. Wait for a few minutes and then try.

6. DISTRIBUTE VACCINES

The objective of good vaccine handling is to minimize:

- The period of time in which all vaccines are exposed to temperatures above +8°C and DPT, DT, and TT vaccines below 0°C
- The period of time in which any vaccine remains in cold chain stores without being used

6.1 Sub-Centre/Village Level

The risk of cold chain failure is greatest at sub-centre and village level. For this reason, the health worker is the most important link in the cold chain. **VACCINES ARE NOT STORED AT THE SUB-CENTRE LEVEL AND MUST BE SUPPLIED ON THE DAY OF USE.**

In order to keep vaccines safe at this level,

- Only required quantities must be supplied
- The vaccine carrier must have frozen ice-packs
- Immunization must be carried out in the shade, and the vaccines (OPV and measles) must be kept on an ice-pack or in a cup of ice during the session
- Only one vial of each vaccine should be out at a time
- Vaccine vials opened for a session must never be used during subsequent sessions
- For each vaccination, single sterile syringe and needle must be used.

The Medical Officer must assign the responsibility of vaccine supplies to a dependable person of the PHC, but the final responsibility for ensuring the cold chain rests on him.

When administering vaccine to expectant mothers and infants at the site of immunization, care must be taken not to expose the vaccine to heat or direct sunlight. To do this the health workers must be instructed to:

- Select a site that is cool as possible, preferably inside a room. If a room is not available, carry out immunization in the shade and not in direct sun.
- Open the carrier only when necessary
- Remove vaccine and diluent from the vaccine container, ONLY when you need it
- Take out only one vial of vaccine from the container at a time. Do not take the second vial from the carrier until it is needed
- Secure the lid tightly after opening as soon as possible
- Wrap the BCG ampoule in a foil or a dark paper to protect them from heat and light
- When vaccine is taken out of the vaccine carrier, vials must be placed on an ice pack. If no mothers or children are waiting, vials must be put back into the vaccine carrier until a beneficiary arrives.

Records on vaccine use must be updated regularly. A record of the vaccines administered must be kept. It is important to record the batch numbers and expiry dates of the vaccines used. If any vaccine is returned to the PHC the reasons for non use must be ascertained and corrective action taken. There should be no reason for returning of unopened vials from the outreach sessions if the sessions are well planned and vaccine issue is based on the estimated number of beneficiaries likely to attend the session. If such vials have been returned in cold chain, these vial should be used first. If there is any doubt about the quality of the reverse cold chain **DO NOT** use the vial.

6.2 PHC Level

Vaccines are delivered to the PHC from the district stores. It is best that vaccines be supplied at regular monthly intervals. This is because a **PHC MUST NOT HOLD MORE THAN ONE MONTH'S STOCK. NO VACCINE SHOULD BE STORED AT THE SUB-CENTRES.**
Vaccine requirements must be estimated so that every infant and pregnant women is immunized, and that adequate supplies are available.

It is important that the right quantity of vaccine is indented. Too little vaccine will result in poor performance. If too much vaccine is obtained, some of them may expire or it may remain for a longer than the recommended time. The longer the vaccines are kept at the PHC, the greater is the risk of a cold chain failure.

WHILE DISTRIBUTING VACCINES FROM THE DISTRICT STORE :

- Choose cold box of appropriate size. In general a cold box (5 litres)

can accommodate one month's supply of PHC of 30,000 population and a cold box (20 litres) for CHC for 1 lakh population.

- Check that the types and amount of vaccine and diluent are the same as indented.
- No vaccines beyond expiry date is to be issued.
- Pack the vaccine in a cold box quickly to avoid exposure to heat and light. Diluent need not be kept in a cold box
- Use the shortest route to the health centre.
- Transfer vaccines to ILR immediately on arrival at the health centre.

WHILE DISTRIBUTING VACCINES FROM THE PHC STORE :

While the vaccines are issued it is important to check the indent to ensure that the demand is based on the estimated beneficiaries likely to attend the session. This will cut down the wastage rate and that the health worker would not have to come back to the PHC to return unused vials.

- Vaccines with nearest expiry date should be issued first.
- Vaccines supplied earlier should be issued first.
- Date expired vaccines should not be issued.
- Check that DPT,DT or TT vaccines have not been frozen. If these have been frozen, do not use them. You can confirm the shake test. Shake the vial so that the sediment is completely mixed into the vial. If the vaccine is not uniformly mixed, or the sediment settles down at the bottom of the vial completely within 15 minutes, then do not use it.
- Diluent must be kept in ILR and issued to the field in Vaccine Carriers.
- The diluent should not be frozen as the ampoule are likely to crack when frozen.
- For the same reasons BCG ampoule should not be frozen.
- The ice packs used for lining the vaccine carriers should be fully frozen

7. MONITOR COLD CHAIN AND USE OF VACCINES

It is essential to regularly monitor cold chain for effective and efficient implementation of the programme.

You will need to monitor

- Supplies
- Storage temperature
- Potency tests

7.1 Supplies

Regular and smooth flow of vaccines and their proper utilization will help to distribute vaccines evenly to all units. Care must be taken to see that there are no over stocking at peripheral units. The PHCs are not to keep vaccines more than the requirement for one month. Similarly district should only keep stock for three months.

The vaccines supply should be based on the estimates, demand and utilization. This information can be easily be obtained from the monthly monitoring format.

Physical check of vaccine stock during supervisory visits should be made. It is necessary to see that the records are properly maintained.

The stock register should be checked in order to assess

- Whether more vaccines are issued than estimated for the session,
- If vaccines have been issued more than 1 day prior to the session,
- Whether all the antigen were available and issued.

7.2 Storage Temparature

Temperature of ILR/Freezer should be recorded twice daily. This should be done by the identified person responsible for storage and issue of vaccine. The Medical Officer should check the record regularly. The break in the cold chain is indicated if temperature rises above +8°C or falls below +2°C

7.3 Potency Tests

Of all the vaccines OPV is the most thermolabile and the potency can be checked by relatively simple laboratory tests. The potency of OPV at the point of use and at various storage points has been taken as **indicator** of the quality of cold chain.

The samples should be collected in vaccine carrier with fully frozen ice packs and rushed to the assigned laboratory.

If delay is anticipated in transmitting the samples for testing, such samples should be kept in the ILR. It is critical the reverse cold chain at a temperature between 2°C - 8°C is maintained during the transportation of the sample from the site of collection to the laboratory.

Facilities for OPV potency testing are currently available at the following centres :

1. Central Research Institute, Kasauli, H.P.
2. National Institute of Communicable Diseases, Delhi
3. Enterovirus Research Centre, Bombay
4. School of Tropical Medicine, Calcutta
5. B.J. Medical College, Ahmedabad
6. Institute of Preventive Medicine, Hyderabad

7. Pasteur Institute, Coonoor, Tamil Nadu
8. King Institute, Guindy, Madras
9. National Institute of Virology, Bangalore
10. Medical College, Jabalpur
11. Institute of Medical Sciences, B.H.U., Varanasi
12. Pasteur Institute, Shillong

GENERAL GUIDELINES FOR COLLECTION AND TRANSPORTATION OF OPV SAMPLES

- The minimum total number of samples to be collected from the State is roughly the number of samples are the same as the number of PHCs in the state.
- About 15% of the samples should be collected from District store and 5 % from Walk-in Coolers.
- The team formed to collect samples should plan their visits in advance and also be responsible for maintenance of the reverse cold chain.
- The staff deployed to lift samples should carry extra vaccine vials in a vaccine carrier so that vaccines collected for testing can be replaced for use at the out-reach sessions.

8. ALTERNATIVE STORAGE ARRANGEMENT - CONTINGENCY PLAN

Cold Chain is dependant on electrically operated machines on which one cannot depend completely. However, sudden problems are unlikely if the equipment are maintained well and used with proper care. Uninterrupted and steady electrical supply is a major requirement for good performance of equipment.

When vaccines cannot be stored at the appropriate temperature due to breakdowns in equipment (WIC/ILR/DFs), or power failure for long periods alternate storage arrangements have to be made in advance to ensure that this contingency is taken care of. The alternate storage locations must be identified in advance.

PLANS FOR EMERGENCY SITUATIONS must be prepared in advance and appropriate sanctions taken so that no time is lost during an emergency. This will help you face such eventualities without any element of panic. The following steps should be taken:

- Identify most suitable alternative arrangement for each equipment.
- List out resources and actions involved and the persons identified to carry out the same.
- Make aware all concerned of the requirements and the activities that may be necessary during emergency and educate/train them accordingly.
- Identify more than one alternative for assurance (stand by arrangement).

ALTERNATIVES FOR EMERGENCY SITUATIONS

Type of failure	Equipment	Primary Health Centre	District
Power failure of longer duration (more than 12 hours)	ILR	Observe temperature of vaccines. If it reaches 8°C, transfer and store them in cold boxes with frozen ice-packs from the freezer	Similar to PHC
	Freezer	As vaccines are not preserved in freezer, no action required.	If vaccines preserved in freezer, transfer them to cold box and preserve with frozen icepacks or commercial ice in polythene bags.
Equipment breakdown (select suitable alternative indicated)	ILR	a) Store in cold boxes with frozen icepacks. b) Transfer to domestic refrigerator if available in the vicinity. c) Transfer to nearby PHC or other departments vaccine storage facility if available	a) Store in cold box with frozen icepacks. b) Transfer to other ILR or Refrigerator available. c) Transfer to any other vaccine storage facility available.
	Freezer	Despatch vaccine : o Using commercial ice, if available locally. o Freeze icepacks in domestic refrigerator/s or in commercial ice factory, if available. o Collect required quantity of frozen icepacks from nearby PHC in cold boxes just on the day or a day ahead of vaccine distribution.	o Store vaccine in ILRs or refrigerator available o Despatch vaccines - similar way as for PHC o Ask recipient of vaccine to bring frozen icepacks while coming
	Voltage Stabilizer	o Preserve vaccine as above o Disconnect stabilizer and obtain replacement immediately from District/ Regional HQ and reconnect.	o Replace from float assemblies immediately from District/Regional HQ stock.

VII STERILIZATION OF EQUIPMENTS

Sterilization of needles and syringes, and other equipments used in an immunization session is absolutely essential. If proper sterilization procedures are not followed, chances of adverse reaction will increase and the credibility of the programme will suffer. If the needles and syringes are not properly sterilized there are chances of transmission of various infections, including HIV/AIDS.

There are several ways of sterilizing syringes and needles. In the programme following methods are used:

1 Steam sterilizer(double rack)
2 Autoclave
3 Boiling

1. STEAM STERILIZER(DOUBLE RACK)

All subcentres have been provided with one steam sterilizer. It consists of following parts sterilizer base, syringe rack, syringe rack lid and sterilizer lid.

1.1 How to Use a Steam Sterilizer:

- Clean the syringes and needles with mild soap water and rinse them with plain water
- Place the barrels, pistons and needles in the holes of the syringe rack
- Put the rack lid on the loaded rack and press the clip so that it fixes with the rack
- Fill water in the sterilizer base upto the mark
- Place the loaded sterilizer rack into the sterilizer
- Put a pairs of forceps on the rack lid
- Put the sterilizer lid on the sterilizer base, matching the arrow marks on the base and the lid and turn it clockwise to close it
- Put the sterilizer on stove.
- As steam starts coming out of pressure valve, wait for 5 minutes , reduce the flame
- Keep it on flame for another 15 minutes
- Remove the sterilizer from the stove and allow it to cool
- Open the lid only when the syringes and needles required
- Turn the lid upside down and keep the forceps on it
- Use the forceps to assemble the syringes

2. AUTOCLAVE

Autoclaves have been provided to most of the PHCs, CHCs and other hospitals. They are used for sterilizing large number of syringes and needles.

HOW TO PACK (FOR AUTOCLAVING)

Packing syringes:

- Wrap each set of barrel, piston and a needles in gauze or cotton cloth.
- For this, cut pieces of gauze 20 cm long from a roll
- Use one piece of gauze for each syringe
- Check that the barrel and the plunger are a pair and that the plunger fits into barrel properly
- Wrap the gauze first around the plunger and then round the barrel
- Pack the gauze-wrapped glass syringes neatly into the container for sterilization
- Put two pairs of forceps into the sterilizer

HOW TO USE AUTOCLAVE

- Put water upto the mark.
- Place autoclave on a stove.
- Open side holes of the dressing drum.
- Put loaded drum in the autoclave.
- Put the lid of the autoclave on the body and tighten the screws diagonally, i.e. tighten the screws opposite one another before going on to the next pair.
- After sometime the needle on the pressure gauge starts moving.
- When it registers 15 lb. pressure (p.s.i.), note the time. Let it remain at 15 lb pressure for 20 minutes.
- Put off the burners.
- Let it cool/let of the steam.
- Remove the lid by loosening the screws on the lid.
- Remove the dressing drum and close the side holes by moving the side wall cover and lock it

3. BOILING

Only when autoclaving or pressure sterilizing is not possible for want of equipment, syringes and needles are sterilized by boiling for at least 20 minutes after water starts boiling. Drain off all the hot water and allow syringes and needles to cool before use, keeping it covered.

Since it takes long time for syringes and needles to cool, try to sterilize them well in advance of the session. Never use hot syringes and needles as heat will destroy the vaccines.

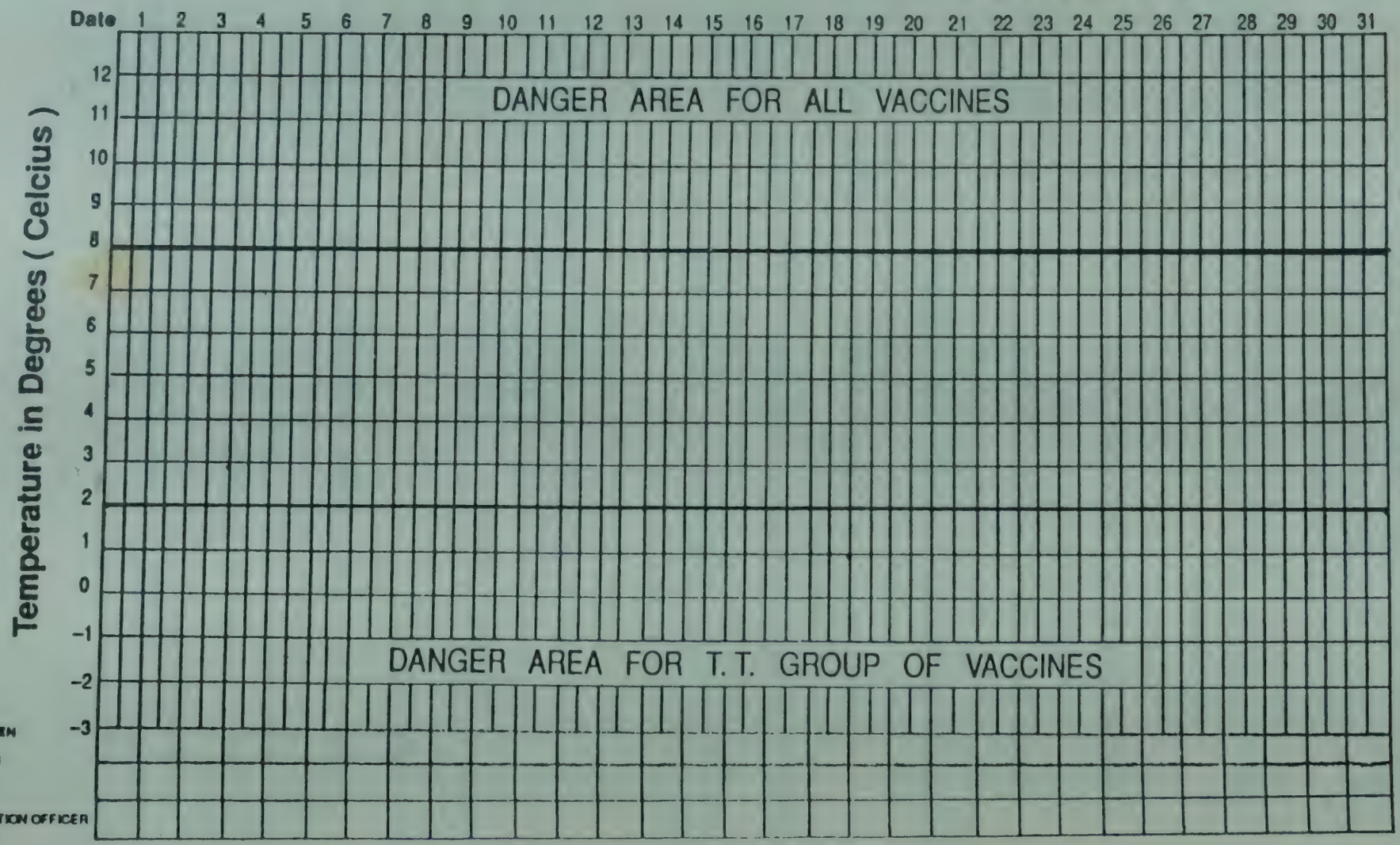
NATIONAL IMMUNIZATION MISSION

राष्ट्रीय टीका कार्यक्रम

TEMPERATURE MONITOR CHART

(REFRIGERATOR I.L.R./ W.I.C.)

MONTH..... P.H.C..... MAKE OF THE UNIT.....
(Eg ILR 240 ILR 140, WIC etc.)



Please answer Yes/No.

A. IS THE REFRIGERATOR
1. LEVEL ?
2. AWAY FROM SUNLIGHT ?
3. LOCKED ?
4. PLUGGED TO SOCKET PERMANENTLY?
5. USED FOR FOOD OR DRU

B. ARE THE VACCINES
1. STACKED NEATLY?
2. ROTATED?
3. FROZEN?
4. DATE EXPIRED?

NO. OF ICE PACKS TAKEN OUT FOR THE USE IN VACCINE/DAY CARRIER

DATE OF DEFROSTING

SIGNATURE OF INSPECTION OFFICER
(SEPIO, CMO, DHO, DIO)

TEMPERATURE RECORD BOOK

NOVEMBER

Please answer : Yes/No
(on last day of the month)

A. Is the refrigerator

1. level? ____
2. away from sunlight? ____
3. locked? ____
4. defrosted periodically? ____
5. plugged to socket permanently? ____
6. used for food or drink? ____

B. Are the vaccines

1. stacked neatly? ____
2. rotated? ____
3. kept in the door? ____
4. frozen? (except polio) ____
5. date expired? ____

C. No. of ice packs prepared during the month ____

D.

	Temperaure > 8°C		
Duration (hours)	1 – 2	3 – 4	5+
Frequency			

Date	Temperature (°C) in refrigerator		Power failure (duration in hours)
	10 am	4 pm	
1			
2			
3			
4			
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31			

Note : Medical officer is to counter sign it once a week.

DECEMBER

Please answer : Yes/No
(on last day of the month)

A. Is the refrigerator

1. level? ____
2. away from sunlight? ____
3. locked? ____
4. defrosted periodically? ____
5. plugged to socket permanently? ____
6. used for food or drink? ____

B. Are the vaccines

1. stacked neatly? ____
2. rotated? ____
3. kept in the door? ____
4. frozen? (except polio) ____
5. date expired? ____

C. No. of ice packs prepared during the month ____

D.

	Temperaure > 8°C		
Duration (hours)	1 – 2	3 – 4	5+
Frequency			

Date	Temperature (°C) in refrigerator		Power failure (duration in hours)
	10 am	4 pm	
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Note : Medical officer is to counter sign it once a week.

EPIDEMIOLOGICAL FEATURES OF VACCINE PREVENTABLE DISEASES

Disease	Causative agent	Mode of transmission	Reservoir	Incubation period	Communicability	Major complications	Specific treatment	Immunity
Poliomyelitis	Polio viruses types I, II and III	Faecally contaminated material Pharyngeal secretions	Man	7-14 days (range 3-25 days)	First week before & after onset of symptoms (range 3-6 weeks)	Residual paralysis of limbs Paralysis of respiratory muscles can lead to death	None	Type specific lifelong
Measles	Measles virus	Air-borne Direct contact with nasal or throat secretions	Man	8-13 days	Slightly before prodromal period to 4 days after rash	Diarrhoea Pneumonia Otitis media Conjunctivitis Encephalitis Malnutrition	None	Life-long
Diphtheria	Corynebacterium diphtheriae	Air-borne Direct contact	Man	2-5 days	2 weeks or less	Respiratory obstruction Myocarditis Nerve Palsies	20,000-100,000 units of antitoxin Antibiotics	Clinical disease may not provide life-long immunity
Pertussis	Bordetella pertussis	Air-borne Direct contact	Man	7-10 days (not exceeding 21 days)	Early catarrhal stage to 3 weeks after onset of symptoms	Brain damage Secondary Infections Malnutrition	Antibiotics	Prolonged
Tetanus	Clostridium tetani	Broken skin	Spores found in soil	3-21 days	Not transmitted directly	Death	Sedatives Muscle relaxants Antibiotics Tetanus immune globulin	Clinical disease does not give immunity
Tuberculosis	Mycobacterium tuberculosis M. africanum M. bovis	Air-borne Raw milk	Man Cattle	4-12 weeks (may persist life-time as latent infection)	Variable (as long as tubercle bacilli being discharged)	Progressive pulmonary disease Meningitis Haematogenous (miliary)	Antimicrobials: Isoniazid and one or more of: Rifampicin, streptomycin ethambutol or pyrazinamide	Variable

GLOSSARY

Crude Birth Rate (CBR)	$\frac{\text{Number of live births during the year}}{\text{Mid-year Population}}$	X 1000
Crude Death Rate (CDR)	$\frac{\text{Number of deaths during the year}}{\text{Mid-year Population}}$	X 1000
Infant Mortality Rate (IMR)	$\frac{\text{Number of infant deaths during the year}}{\text{Number of live births during the year}}$	X 1000
Still Birth Rate (SBR) (IMR)	$\frac{\text{Number of still births during the year}}{\text{Number of live births + still births during the year}}$	X 1000
Peri-natal mortality Rate (PMR)	$\frac{\text{Number of still births + infant deaths of less than 7 days during the year}}{\text{Number of live births + still births during the year}}$	X 1000
Neo-natal mortality Rate (NMR)	$\frac{\text{Number of infant deaths of less than 28 days during the year}}{\text{Number of live births during the year}}$	X 1000
Post Neo-natal Mortality Rate (PNMR)	$\frac{\text{Number of infant deaths of over 28 days during the year}}{\text{Number of live births during the year}}$	X 1000
Age-specific Mortality Rate (ASMR)	$\frac{\text{Number of deaths in a particular age-group}}{\text{Mid-year population of the same age-group}}$	X 1000